

REMARKS/ARGUMENTS

Claims 1-47 are pending. Claim 7 has been amended. New claims 48-50 are added.

Claim Amendments

Claim 7 has been amended. New claims 48-50 are added. These amendments and claims are supported by the specification, *inter alia*, by Figures 72-73 and 37-38. No new matter is added.

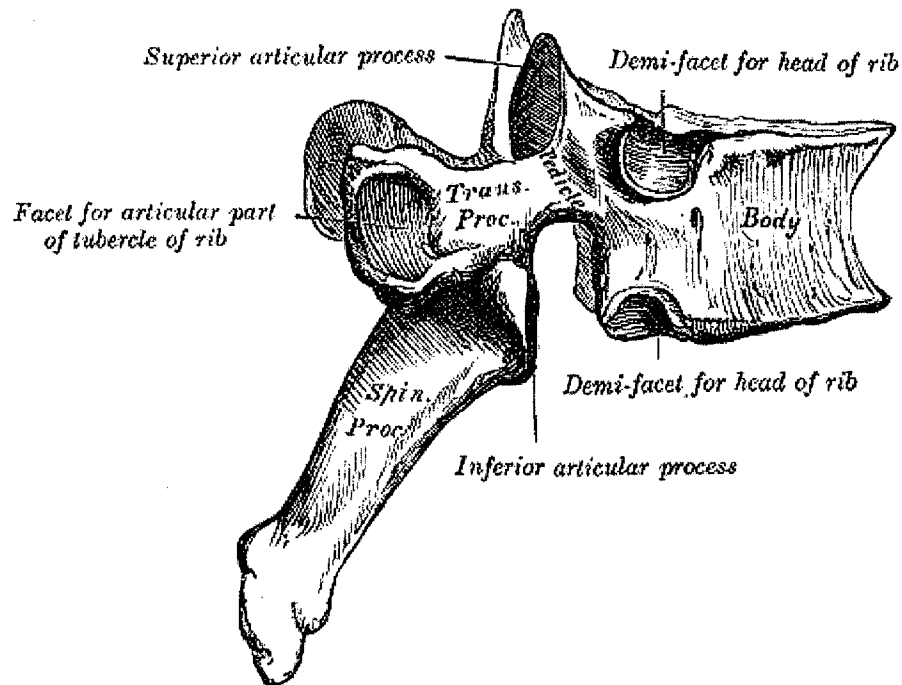
35 U.S.C. § 102 Rejection

Claims 1-47 were rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent 5,562,662 to Brumfield et al. ("Brumfield"). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). *See* MPEP § 2131. In this case, Brumfield does not anticipate the claims because Brumfield fails to describe each and every element of the claims.

Before addressing the claims in particular, Applicant feels a review of spinal anatomy would be useful. According to Gray's Anatomy (2003) Vertebrae, pp. 34-35:

Each vertebra consists of two essential parts—an anterior solid segment or body, and a posterior segment or arch. The arch (neural) is formed of two pedicles and two laminae, supporting seven processes— viz. four articular, two transverse, and one spinous. . . . The Spinous Process projects backward from the junction of the two laminae, and serves for the attachment of muscles and ligaments.

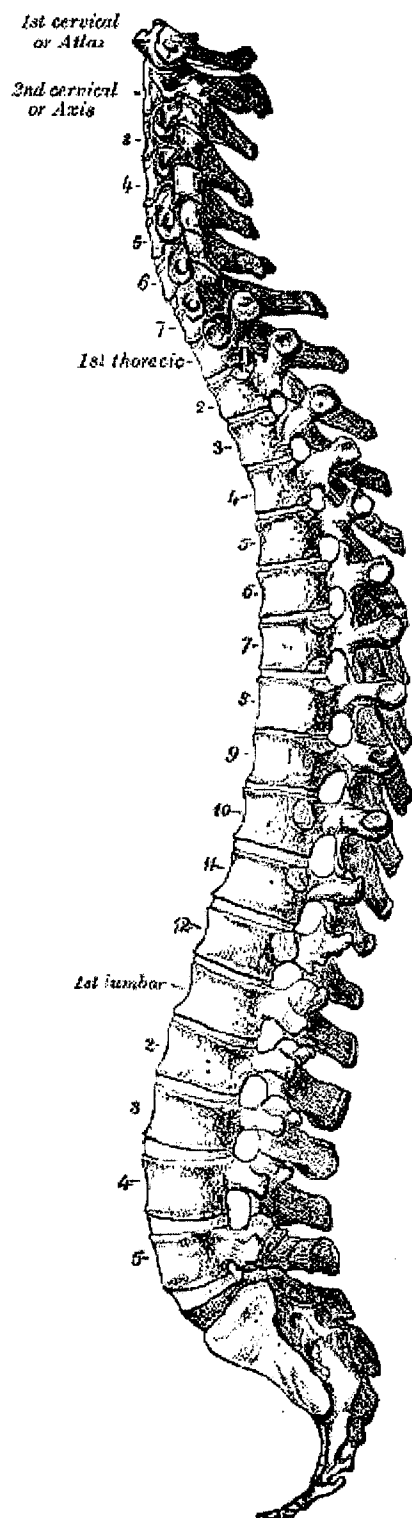
A figure of a dorsal vertebra is reproduced below to show the position of the spinous process (Spin. Proc.) (Gray's Anatomy Fig. 5. —A dorsal vertebra.):



When the vertebra is shown in the context of the spine, one can see that the spinous process is the one that projects backward from the body of each vertebra (Gray's Anatomy Fig. 22.—Lateral view of the spine.):

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Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 3733

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Independent Claims 1 and 7

Each of independent claims 1 and 7 requires a step of causing the interspinous process implant inserted by the inserting step to deploy. The specification describes that the interspinous process implant can include features "that maintain the position of the device between the spinous processes in order to limit extension without limiting flexion. Such features may be projected or deployed after the device is implanted between the spinous processes" Paragraph [0008] of published application (emphasis added). Exemplary Figs. 72 and 73 depict an embodiment having arms (640, 642) that deploy, that is, they "project outwardly from the central body in order to hold the implant in position between the spinous processes." [0127] (emphasis added). In independent claims 1 and 7, the interspinous process implant inserted (laterally) deploys.

Turning to the cited prior art, the Examiner states that "[t]he device of Brumfield et al. can be considered to be deployed, since it is being utilized and arranged for a deliberate purpose (i.e. to draw the rods 21 together, column 10, lines 10-14) and is adjacent to the spinal [sic?] processes on both sides (Fig. 2)." Final Office Action at p. 2.

A.. Brumfield does not disclose an interspinous process implant that is both laterally inserted and deployed.

Brumfield does not disclose an interspinous process implant that deploys adjacent to a spinous process. The Examiner states that the Brumfield device is "adjacent to the spinal [sic?] processes on both sides (Fig. 2)." Final Office Action at p. 2. The Examiner apparently is referring to the spinal rods 21 that run vertically parallel in Brumfield Fig. 2. However, the spinal rods are not between spinous processes, and thus cannot constitute an interspinous process implant, much less an interspinous process implant that deploys.

The only feature of Brumfield that occupies space between spinous processes is transverse connector 38, which laterally connects the spinal rods. However, the transverse connector does not deploy adjacent to a lateral side of at least of the upper and the lower spinous processes. As shown by Brumfield Fig. 2, the transverse connector 38 does not occupy any

space adjacent to the upper or lower spinous processes; the transverse connector does not deploy into this space.

In other words, the transverse connector is between spinous processes, but it does not deploy. Conversely, the spinal rods are adjacent to the lateral side of a spinous process, but they are not inserted laterally between spinous processes. Brumfield does not disclose an interspinous process implant that deploys as required by the present claims. Note that claims 1 and 7 recite an implant that is both a) inserted laterally between spinous processes and b) deployed.

B. Brumfield does not disclose an implant that deploys adjacent a second lateral side of a spinous process.

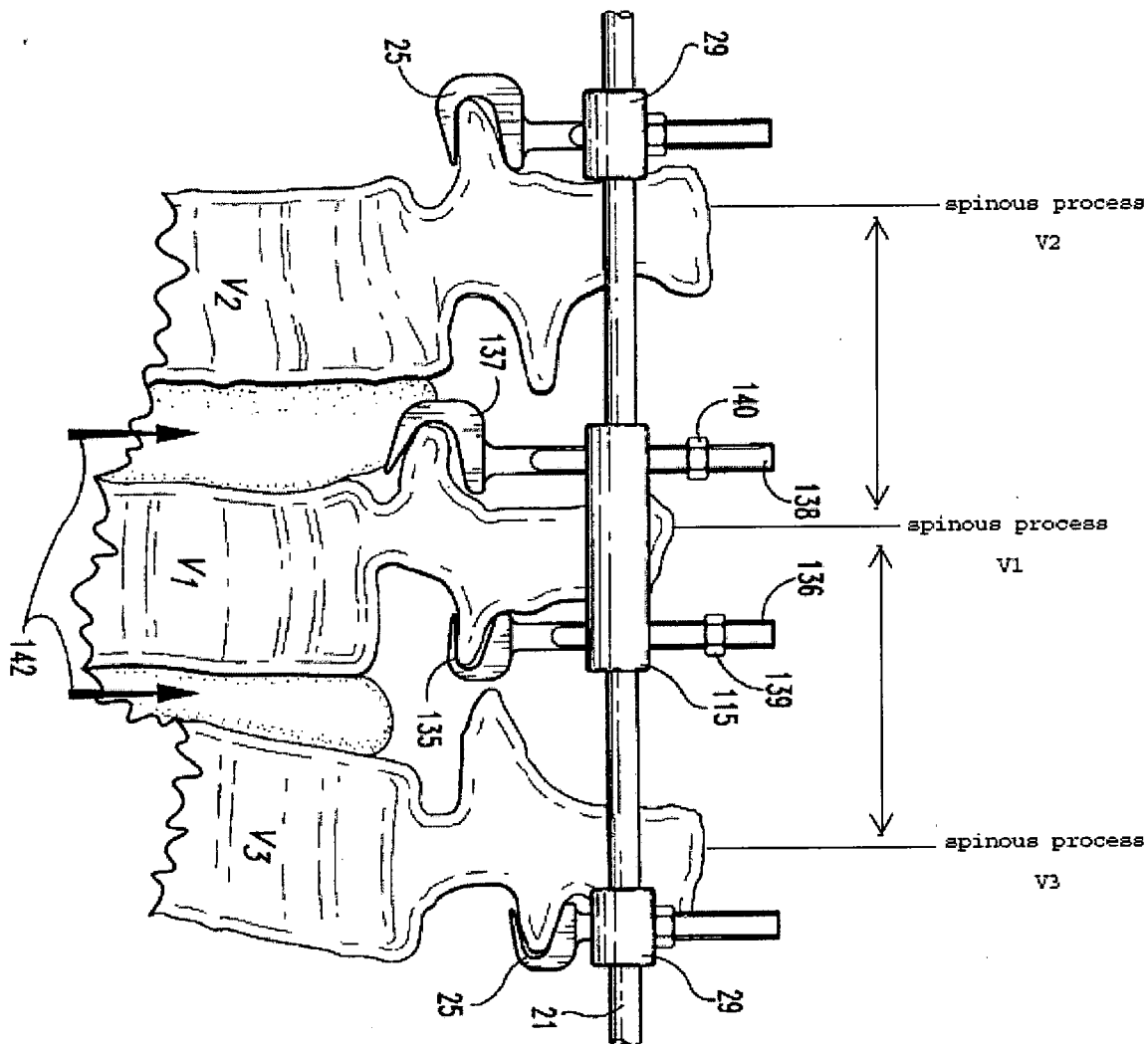
Each of claims 1 and 7 require deployment adjacent a second lateral side of at least one of the spinous processes. Although the deployed feature of the claimed invention need not touch the spinous processes, the spinal rods 21 of Brumfield are necessarily and significantly spaced away from the spinous processes because they instead engage the lamina of the vertebra. As shown by Brumfield Fig. 2, the Brumfield device gives a wide berth surrounding all sides of the spinous processes; thus, it does not deploy adjacent to a lateral side of a spinous process.

C. Brumfield does not disclose a distracting step.

With respect to dependent claims 2 and 3, the Examiner refers to Brumfield Figs. 12 and 3C as disclosure of a distracting step. Final Office Action at p. 3. But neither of these figures discloses any feature that even exists in the interspinous process space. The features referenced by the Examiner, ref. 27 (Fig. 3C) and ref. 137 (Fig. 12), are hooks designed to engage the lamina, not a spinous process: "[T]he hooks can be a hook such as hook 25 having a stem 26, as well as a differently configured laminar hook 116 having a stem 117. The two hooks can have their claws facing each other to engage the lamina of a vertebra therebetween." Brumfield col. 10, lines 19-22 (emphasis added). Thus, Figs. 12 and 3C are wholly irrelevant to an interspinous process implant.

Furthermore, Fig. 12 does not depict distracting apart spinous processes. Fig. 12 depicts moving a displaced vertebra outward toward the spinal rod in the direction of the arrows

142. Col. 11, lines 42-45. Fig. 12 does not depict moving the spinous process of V1 away from the spinous process of either V2 or V3. Rather, the vertebrae maintain their respective longitudinal spacing while V1 is moved outward as depicted by arrows 142. Brumfield Fig. 12 is reproduced below, rotated to show how the vertebra would be vertically positioned in the spine and labeled to show how the distances between interspinous processes are maintained.



To sum, Brumfield does not disclose an interspinous process implant that deploys adjacent to a second lateral side of a spinous process. At least because Brumfield fails to disclose this element of independent claims 1 and 7, Brumfield fails to anticipate these claims and similarly, the claims that depend therefrom. Brumfield further fails to anticipate dependent

claims 2 and 3 because it fails to disclose a distracting step. Applicant respectfully requests that the anticipation rejection be withdrawn. To expedite prosecution, applicants have further amended claim 7 to recite that the implant deploys "so that a member of the interspinous process implant projects outwardly from a body of the interspinous process implant." These elements are clearly allowable over the Brumfield reference for the reasons given above.

Independent Claims 8 and 15

Each of independent claims 8 and 15 requires a deployment step where the implant or implant member " extends from a second lateral side of the spinous process." The Examiner states that Brumfield discloses "inserting the interspinous process implant (Fig. 2, ref. 20) . . . where the interspinous process implant extends from a second lateral side (Fig. 2, since it extends along both lateral sides)." Final Office Action at p. 4. The Examiner apparently is referring to the spinal rods, feature 21, that run vertically parallel. However, the spinal rods are not inserted between the spinous process, and thus cannot constitute an interspinous process implant, much less one that extends from a second lateral side.

As discussed above with respect to claims 1 and 7, the Examiner appears to be mixing and matching the characteristics of different Brumfield features in a piecemeal attempt to recreate the claimed invention. The only Brumfield feature located in the interspinous process space is the transverse connector, but this feature does not extend as required by the present claims.

With respect to dependent claims 9, 10, 16, and 17, Brumfield additionally fails to anticipate these claims because it fails to disclose a distracting step as discussed above.

Thus, Brumfield does not disclose an interspinous process implant (or a deployable member thereof) that extends from a second lateral side of a spinous process. At least because Brumfield fails to disclose this element of independent claims 8 and 15, Brumfield fails to anticipate these claims and similarly, the claims that depend therefrom. Applicant respectfully requests that the anticipation rejection be withdrawn.

Independent Claims 23, 28, 33

Each of independent claims 23, 28, and 33 require a distraction guide.

The Examiner refers to Brumfield Fig. 2, ref. 25 as disclosure of distraction guide. However, ref. 25 is a fixation hook having a claw for engaging the lamina of a vertebra. Col. 10, lines 19-22. The fixation hood described in Brumfield does not contact a spinous process at all, nor does it occupy the space between spinous processes. Thus, fixation hook 25 cannot be a distraction guide. Furthermore, the fixation hook 25 in no way extends from the distal end of a body adapted to be placed between spinous processes. Even assuming *arguendo*, that the transverse connector 38 is placed between spinous processes, the fixation hook 25 in does not extends from the distal end thereof. In short, Brumfield does not disclose any feature related to distraction of spinous processes. Thus, Brumfield does not anticipate these claims, not the claims that depend therefrom. Accordingly, Applicant respectfully requests that the anticipation rejection be withdrawn.

Independent Claim 38

Independent claim 38 requires, *inter alia*, two saddles adapted to receive spinous processes. The Examiner mistakenly refers to Brumfield ref. 28, the rod connector means, as a saddle. But the rod connector means does not receive a spinous process. Brumfield Fig. 2. In fact, no Brumfield feature receives a spinous process. Note the empty space along both sides of the spinous processes, which project outward toward the viewer. See Brumfield Fig. 2

As discussed above with reference to claims 1 and 7, the Examiner points to Brumfield Fig. 12 as disclosure of distraction. However, as explained above, Fig. 12 is wholly irrelevant to the present claims because Fig. 12 does not depict any interspinous process implant. No feature occupies the space between spinous processes, and no feature distracts the spinous processes apart from one another.

Because Brumfield entirely lacks any feature(s) adapted to receive adjacent spinous processes, Brumfield does not anticipate claim 38 and similarly, the claims that depend therefrom. Applicant respectfully requests that the anticipation rejection be withdrawn.

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CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 202-481-9914.

Respectfully submitted,



Dana Buschmann
Reg. No. 54,567

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TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 202-481-9914
Fax: 202-481-3972
Attachments
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